



[Billing Code 6335-01]

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0040]

16 CFR Part 1199

Children's Toys and Child Care Articles Containing Phthalates; Final Guidance on Inaccessible Component Parts

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. Section 108 of the CPSIA, as amended by Public Law 112-28, provides that the prohibition on specified products containing phthalates does not apply to any component part of children's toys or child care articles that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product. In this document, the Consumer Product Safety Commission (CPSC or Commission) issues guidance on inaccessible component parts in children's toys or child care articles subject to section 108 of the CPSIA.

DATES: This rule is effective [Insert date of publication in the **Federal Register**].

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SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

On August 14, 2008, Congress enacted the CPSIA (Pub. L. 110-314), as amended on August 12, 2011, by Pub. L. 112-28. Section 108 of the CPSIA, titled, “Prohibition on Sale of Certain Products Containing Specified Phthalates,” permanently prohibits the sale of any “children's toy or child care article” containing more than 0.1 percent of three specified phthalates (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child’s mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). These prohibitions became effective on February 10, 2009. 15 U.S.C. 2057c(a), (b). The terms or phrases “children’s toy,” “toy that can be placed in a child’s mouth,” and “child care article,” are defined in section 108(g) of the CPSIA. A “children's toy” is defined as a “consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.” A toy can be placed in a child’s mouth “if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children’s product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in a child’s mouth.” The term “child care article” means “a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 years and younger, or to help such children with sucking or teething.” 15 U.S.C. 2057c(g).

Section 108(d) of the CPSIA provides that the prohibitions for the specified phthalates shall not apply to any component part of a children's toy or child care article that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. That section further provides that a component part is not accessible, if such component part is not physically exposed, by reason of a sealed covering or casing, and does not become physically exposed through reasonably foreseeable use and abuse of the product. Reasonably foreseeable use and abuse includes swallowing, mouthing, breaking, or other children's activities, and the aging of the product. 15 U.S.C. 2057c(d)(1).

The CPSIA directs the Commission to: (A) promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible; or (B) adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth. 15 U.S.C. 2057c(d)(3).

Section 108 of the CPSIA also directed the Commission, not earlier than 180 days after the date of enactment of this Act [enacted Aug. 14, 2008], to appoint a Chronic Hazard Advisory Panel (CHAP), pursuant to the procedures of section 28 of the CPSA (15 U.S.C. 2077), to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles. 15 U.S.C. 2057c(b)(2). The Commission appointed the CHAP on April 14, 2010, to study the effects on children's health of all phthalates and phthalate alternatives, as used in children's toys and child

care articles. The CHAP currently is working on a report, including recommendations, to be sent to the Commission.

Under section 108(d)(2) of the CPSIA, the Commission may revoke any or all exclusions granted based on the inaccessible component parts provision of section 108 of the CPSIA, at any time, and require that any or all component parts manufactured after such exclusion is revoked, comply with the prohibitions of phthalates, if the Commission finds, based on scientific evidence, that such compliance is necessary to protect the public health or safety. 15 U.S.C. 2057c(d)(2).

2. Notice of Proposed Guidance

In the *Federal Register* notice of July 31, 2012 (77 FR 45297), the Commission published a proposed guidance on inaccessible phthalate-containing component parts. As stated in the preamble to the proposed guidance (77 FR 45299), the Commission proposed to adopt the lead guidance for determining inaccessible component parts for phthalates, with the exception of polyvinyl chloride (PVC or vinyl) or other plasticized materials covering mattresses and other sleep surfaces designed or intended by the manufacturer to facilitate sleep of children age 3 and younger. Both the lead guidance and proposed phthalate guidance specified that a children's product, toy, or child care article that is completely enclosed or covered by fabric is considered inaccessible to a child, unless the product or part of the product in one dimension is smaller than 5 centimeters. However, the lead guidance did not exclude vinyl or other plasticized materials covering mattresses and other sleep surfaces. The proposed phthalate guidance found that while lead is unlikely to leach through fabric except in the case of mouthing or swallowing an item, sheets or mattress pads that cover a vinyl sleep or other plasticized

sleep surface should not serve as a barrier to the potential exposure of phthalates for young children. A child's skin comes into close contact with mattresses and similar products for large portions of a day, and a mattress cover could be dampened with a spilled beverage, saliva, sweat, urine, or other liquid, which could facilitate phthalate migration through a fabric covering. 74 FR 39539 (August 7, 2009).

In addition, although section 108 did not specifically disqualify paint, coatings, or electroplating as barriers that would render phthalates inaccessible, the Commission proposed to adopt the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead. The proposed phthalates guidance stated that paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. The proposed phthalates guidance also noted that in some applications, phthalates are added to paint, printing inks, or coatings. 77 FR45299.

In addition, the Commission determined preliminarily that:

- An accessible component part is one that is capable of being touched or mouthed by a child;
- An inaccessible component part is one that is located inside the product and not capable of being touched or mouthed by a child, whether or not such part is visible to a user of the product;
- An inaccessible part is one that may be enclosed in any type of material, *e.g.*, hard or soft plastic, rubber, or metal (with the exception of vinyl or other plasticized

materials covering mattresses or other sleep surfaces for children age 3 and younger);

- To assess whether a part is inaccessible, the accessibility probes defined in the Commission’s existing regulations for evaluating accessibility of sharp points or sharp metal or glass edges (16 CFR 1500.48 and 1500.49) are appropriate. An “accessible phthalate-containing component part” would be considered one that contacts any portion of the specified segment of the accessibility probe. An “inaccessible phthalate-containing component part” would be considered as one that cannot be contacted by any portion of the specified segment of the accessibility probe; and
- Use and abuse tests are appropriate for evaluating whether phthalate-containing component parts of a product become accessible to a child during normal and reasonably foreseeable use and abuse of the product by a child (with the exception of the bite test). The purpose of the tests is to simulate use and damage or abuse of a product by children and to expose potential hazards that might result from use and abuse. 16 CFR 1500.50-1500.53.

B. Discussion of Comments to the Proposed Guidance and CPSC’s Responses

Five comments were received on the proposed guidance. Two of the comments were from industry and three from consumers or nonprofit consumer and public health organizations. Most comments express general support for the guidance.

1. Fabric materials as a barrier to accessibility of component parts

Comment: One commenter states that fabric should not be considered a barrier, regardless of the size of the component, because children could be exposed to phthalates through the fabric.

Response: As provided in CPSC staff's briefing memo "Guidance for Evaluating Accessibility of Phthalate-Containing Component Parts" dated July 13, 2012, CPSC staff is not aware of any studies that show the propensity for phthalates to move from a phthalate-containing material through an intact, non-phthalate-containing material, such as an outside covering, where it could eventually reach the outside of a product. Furthermore, CPSC staff's review showed that the non-vapor passive movement of phthalates within a product, if it exists, would be exceedingly slow and would never account for any more than a small, negligible fraction of the original phthalate content of the inaccessible phthalate-containing part. Based on CPSC staff's analysis, the Commission finds that, in most cases, phthalates that are inaccessible would not result in physical exposure to phthalates, unless it is reasonably foreseeable that a component part will become physically exposed through mouthing, swallowing, breaking, or other children's activities, and aging of the product. Accordingly, a children's toy or child care article that is, or contains, a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product, or part of the product, in one dimension, is smaller than 5 centimeters; *i.e.*, a fabric-covered component part is not inaccessible if the product, or part of the product, can be placed in a child's mouth.

Moreover, the Commission reiterates that vinyl or other plasticized materials

covering mattresses and other sleep surfaces designed or intended by a manufacturer to facilitate sleep for children age 3 and younger should not be considered to be made inaccessible through the use of a fabric covering. As discussed in the preamble of the proposed guidance, the Commission reviewed phthalate-containing vinyl or other plasticized materials covering mattresses and sleep surfaces intended for young children. These mattresses or sleep surfaces are too large to be placed in a child's mouth. Although such mattresses or sleep surfaces may be covered by fabric, such as sheets or mattress pads, additional consideration was given to whether children would become physically exposed to the vinyl or other plasticized materials covering the surface through reasonably foreseeable use and abuse of the products, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product. The Commission determined there may be instances in which a child's skin comes into close contact with a fabric covering over a phthalate-containing item for large portions of a day, such as a vinyl or other plasticized material covering a mattress or other sleep surface. Young children typically spend more than half of each day sleeping or resting, frequently on a mattress or similar item. While a mattress is typically covered with a sheet or mattress pad, such non-permanently affixed coverings that are either supplied with the mattress or provided by the consumer should not be considered to render the underlying material inaccessible. As with the potential transfer of phthalates by saliva during mouthing of an item, a mattress cover dampened with a spilled beverage, saliva, sweat, urine, or other liquid, could facilitate phthalate migration through the fabric. Furthermore, a nonpermanent covering cannot be assumed to be in use at all times; if it is not, the mattress could no longer be considered inaccessible. For these reasons, vinyl (or other

plasticized material) covered mattresses/sleep surfaces, which contain phthalates, designed or intended by a manufacturer to facilitate sleep for children age 3 and younger, should not be considered to be made inaccessible through the use of a fabric covering.

Comment: One commenter states that the proposed guidance “exempts components covered in fabric provided that the underlying component is not smaller than 5 centimeters in any one dimension.” According to the commenter, any exposure to phthalates-containing component parts within fabric coverings is very low and all phthalate-containing components parts covered by fabric should be exempt, irrespective of the size of the part. The commenter also suggests that a *de minimis* exception should be considered for accessible small plasticized parts.

Response: The commenter misinterprets the fabric covering restriction in the proposed guidance on inaccessible phthalate-containing component parts. The proposed guidance states that “a children’s product that is or contains a phthalate-containing part which is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is inaccessible to a child unless the product or part of the product in one dimension is smaller than 5 centimeters.” However, the 5 centimeter measure is applied to the fabric-covered part or product (i.e., a fabric covered plastic button), not to the size of the underlying phthalate-containing component part. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in a child’s mouth (i.e., a fabric covered plastic ear on a stuffed animal). A phthalate-containing component part which is encased by a fabric covering is considered to be accessible to a child if the part or product is smaller than 5 centimeters in any dimension because such a part or product could be placed in a child’s mouth, and the fabric is not expected to perform as a barrier

to saliva or other fluids or to prevent direct contact by the child with the saliva or other fluid after a fluid's contact with the phthalate-containing part. Even if a fabric covering passes the applicable use and abuse tests, such a covering is not a barrier to the underlying material if the product can be placed in the mouth because it is smaller than 5 centimeters.

If the phthalate-containing component part that is encased by fabric covering is 5 centimeters or greater in dimension, such a part of product is considered to be inaccessible to a child, because the part or product is not likely to be put in the mouth or swallowed (i.e., plastic electronic box inside a stuffed animal). As discussed above, however, vinyl or other plasticized material covering a mattress or other sleep surface which is designed or intended by a manufacturer to facilitate sleep of children age 3 and younger, even when covered with a sheet or mattress pad, will still be considered accessible given that the foreseeable use and abuse of the product, including spilled beverages, saliva, sweat, urine, or other liquids, may facilitate phthalate migration through the fabric.

The statute does not provide for a *de minimis* exception for accessible component parts, and the Commission is not considering in this guidance such exceptions for accessible phthalate-containing children's toys and child care articles. However, we note that a CHAP has been convened to study the effects on children's health of all phthalates and phthalate alternatives, as used in children's toys and child care articles. Based on the findings and recommendations of the CHAP, any guidance concerning phthalates may be modified and revised, as appropriate.

Comment: The same commenter also states that the exclusion of fabric materials as a barrier to accessibility for phthalate-containing parts or products smaller than 5 centimeters is inconsistent with the Commission's use and abuse testing.

Response: The proposed guidance provides that accessibility of component parts, as a result of normal and reasonably foreseeable use and abuse of the product, should be evaluated using the use and abuse tests under the Commission's regulations at 16 CFR 1500.50 through 1500.53 (excluding the bite test in paragraph (c) of §§ 1500.51–1500.53). We disagree that the exclusion of fabric materials as a barrier to accessibility is inconsistent with the Commission's use and abuse testing. The Commission finds, in general, that fabric coverings can be considered barriers to the underlying materials because such coverings prevent direct physical contact with the phthalate-containing parts. The appropriate use and abuse tests, such as the test for the integrity of seams, should be used to evaluate fabric coverings to ensure that the component parts remain physically inaccessible to a child. Use and abuse testing generally is applied to evaluate whether a component part may become physically accessible as a result of reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children's activities. Historically, this testing has been used to evaluate the presence of physical hazards, such as small parts, which may be choking hazards, or sharp points and edges. In the case of lead-containing or phthalate-containing component parts, these tests are used to evaluate the potential for physical contact with the parts. The material beneath a fabric covering should not be considered to be inaccessible to a child if the part or product is smaller than 5 centimeters in any dimension because such a part or product could be placed in a child's mouth, and fabric is not expected to perform

as a barrier to saliva or other fluids or to prevent direct contact by the child with the saliva or other fluid after a fluid's contact with the phthalate-containing part. Even if a fabric covering passes the applicable use and abuse tests, such a covering is not a barrier to the underlying material if the product can be placed in the mouth.

2. Exclusion of the “Bite Test” from use and abuse testing

Comment: Two commenters question the exclusion of the “bite test” from the use and abuse testing and requested that it be included in the guidance.

Response: Currently, the Commission does not use the bite test specified in 16 CFR 1500.51–1500.53), as a result of a court case (*Clever Idea Co., Inc. v. Consumer Product Safety Commission*, 385 F. Supp. 688 (E.D. N.Y. 1974)) that questioned the appropriateness of this test. Because the bite test currently is not applied as part of use and abuse testing for consumer products, it will not be applied for the purposes of evaluating products for accessibility of phthalate-containing component parts. However, this requirement may be modified in a future proceeding if the bite test is reevaluated.

3. Requirements for labeling of art materials

Comment: One commenter requests consistency among the requirements for paints and other surface coatings for lead and phthalates and the requirements under ASTM D 4236 and ASTM F 963 that address art materials. This commenter specifically requests that bottles of paint available in retail stores should comply with all requirements because such paint could be used by children or on products for children.

Response: This comment is outside the scope of this guidance, which addresses the issue of when a phthalate-containing component part of a children's toy or child care

article is considered to be inaccessible to a child. The *Standard Consumer Safety Specification for Toy Safety*, ASTM F 963 requires that all art materials comply with the Labeling of Hazardous Art Materials Act (LHAMA). In addition to the LHAMA requirements discussed above, art materials that are designed or intended primarily for children 12 years of age or younger, are also required, like all children's products, to comply with the requirements of the CPSIA, including third party testing and certification.

C. Effective Date

Although guidance documents do not require a particular effective date under the Administrative Procedure Act, 5 U.S.C. 553(d)(2), the Commission recognizes the need for providing the guidance expeditiously. In addition, material published in the Code of Federal Regulations must have an effective date. Accordingly, the guidance will take effect upon publication in the *Federal Register*.

D. Final Guidance

The Commission is issuing the final guidance without substantive change from the proposed guidance.

List of Subjects in 16 CFR Part 1199

Business and industry, Infants and children, Consumer protection, Imports, Toys
For the reasons stated above, the Commission adds 16 CFR part 1199 to read as follows:

PART 1199- CHILDREN'S TOYS AND CHILD CARE ARTICLES CONTAINING PHTHALATES: GUIDANCE ON INACCESSIBLE COMPONENT PARTS

Authority: 15 U.S.C. 1251–1289, 86 Stat. 1207, 125 Stat. 273.

§ 1199.1 Children’s toys and child care articles: phthalate-containing inaccessible component parts.

(a) Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits the sale of any “children’s toy or child care article” containing more than 0.1 percent of three specified phthalates (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child’s mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). A “children’s toy” is defined as a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays. A toy can be placed in a child’s mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children’s product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth. The term “child care article” means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 years and younger, or to help such children with sucking or teething.

(b) Section 108(d) of the CPSIA provides that the prohibitions in paragraph (a) of this section do not apply to component parts of a children’s toy or child care article that are not accessible to children through normal and reasonably foreseeable use and abuse

of such product, as determined by the Commission. A component part is not accessible if it is not physically exposed, by reason of a sealed covering or casing, and does not become physically exposed through reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

(c) Section 108(d)(3) of the CPSIA directs the Commission to promulgate a rule to provide guidance with respect to what product components or classes of components will be considered to be inaccessible for a children's toy or child care article that contains phthalates or adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth. 15 U.S.C. 2057c(d)(3). The Commission adopts the same guidance with respect to inaccessibility for the phthalates that was adopted by the Commission with regard to accessibility of lead, however, vinyl (or other plasticized material) covered mattresses/sleep surfaces, that contain phthalates that are designed or intended by the manufacturer to facilitate sleep of children age 3 and younger, are considered accessible and would not be considered inaccessible through the use of fabric coverings, including sheets and mattress pads.

(d) The accessibility probes specified for sharp points or edges under the Commission's regulations at 16 CFR 1500.48–1500.49 should be used to assess the accessibility of phthalate-containing component parts of a children's toy or child care article. A phthalate-containing component part would be considered accessible if it can be contacted by any portion of the specified segment of the accessibility probe. A

phthalate-containing component part would be considered inaccessible if it cannot be contacted by any portion of the specified segment of the accessibility probe.

(e) For children's toys or child care articles intended for children that are 18 months of age or younger, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.51 (excluding the bite test of § 1500.51(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children's toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(f) For children's toys or child care articles intended for children that are over 18 months, but not over 36 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.52 (excluding the bite test of § 1500.52(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children's toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(g) For children's toys intended for children that are over 36 months, but not over 96 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of § 1500.53(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children's toy as a result of normal and reasonably foreseeable use and abuse of the product.

(h) For children's toys intended for children over 96 months through 12 years of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of § 1500.53(c)) intended for children ages 37–96 months should be used to evaluate accessibility of phthalate-containing component

parts of a children's toy as a result of normal and reasonably foreseeable use and abuse of the product.

(i) Because the Commission adopts the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead, paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. A children's toy or child care article that is or contains a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters. However, vinyl (or other plasticized material) covered mattresses/sleep surfaces that contain phthalates that are designed or intended by the manufacturer to facilitate sleep of children age 3 and younger, are considered accessible and would not be considered inaccessible through the use of fabric coverings, including sheets and mattress pads.

(j) The intentional disassembly or destruction of products by children older than age 8 years, by means or knowledge not generally available to younger children, including use of tools, will not be considered in evaluating products for accessibility of phthalate-containing components.

Dated: February 11, 2013

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

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